



#10/BM
96-01

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Gi Yong YOO

Serial No.: 09/295,850

Group No.: 1731

Filed: April 21, 1999

Examiner.: M. Halpern

For: TOBACCO SUBSTITUTE COMPOSITION

Attorney Docket No.: U 012218-7

**Assistant Commissioner for Patents
Washington, D.C. 20231**

Sir:

RECEIVED
SEP 5 2001
TC 1700

SUPPLEMENTAL RESPONSE

This is a supplemental response to the Notice of Appeal filed on July 9, 2001.

The present application discloses a composition comprising 80-90 weight percent of *Encommia ulmoides*, 1-10 weight percent of *Glycyrrhiza glabra*, and 1-10 weight percent of *Perilla frutescens*. The present composition is a tobacco substitute and is an effective aid in smoking cessation. *Glycyrrhiza glabra* and *Perilla frutescens* are combined with *Eucommia ulmoides* for their "medicinal" purposes. Often a person who is in the process of quitting smoking will experience side effects such as coughing and will expectorate sputum.

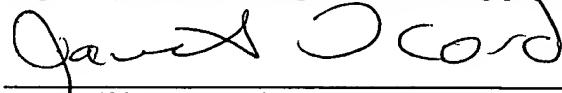
Glycyrrhiza glabra serves to discharge sputum and smooth the airways of a patient who is smoking the composition to overcome the side effects which may occur due to cessation of smoking, see the paragraph bridging pages 2 and 3 of the new specification.

CERTIFICATE OF MAILING (37 CFR 1.8a)

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal on the date shown below with sufficient postage as first class mail in an envelope addressed to the: Assistant Commissioner for Patents, Washington, D.C. 20231

Janet I. Cord

Type or print name of person mailing paper



(Signature of person mailing paper)

Date: August 29, 2001

Perilla frutescens is added to the composition to overcome the coughing effects associated with cessation of smoking, see page 3, lines 3-6 of the new specification.

According to the Examiner, the present invention is obvious in light of Shin (KR 9007855B) in view of Webster's 3rd New International Dictionary, Finberg (U.S. Patent No. 2,930,719) and Horimoto (U.S. Patent No. 4,620,554).

The Shin reference describes a tobacco substitute composition comprising *Eucommia ulmoides*, licorice, honey and peppermint mixture. The Shin reference is silent about using *Perilla frutescens*. The Finberg reference teaches using licorice as a flavorant at 4%. The Examiner argues that it would have been obvious to add the licorice to the tobacco substitute composition of Shin because it would accomplish the desired results of flavoring the composition. Horimoto teaches using Beefsteak, Japanese mint, peppermint and vanilla interchangeably as flavorants in a smoking composition. The Examiner alleges that it would have been obvious to combine Beefsteak and Japanese mint with the composition of Shin because the aseptic action and tasteful properties of Beefsteak and the refreshing feel and taste properties of Japanese mint, would provide further flavoring in the Shin tobacco substitute.

None of the cited prior art references describe *Glycyrrhiza glabra* and *Perilla frutescens* to overcome the side effects associated with the cessation of smoking. Rather the prior art references, as well as the arguments set forth by the Examiner, describe *Glycyrrhiza glabra* and *Perilla frutescens* as flavorants.

Enclosed are papers disclosing the medicinal properties of *Glycyrrhiza glabra* and *Perilla frutescens*. These papers support the position that these components act as something more than flavorants.

In the *Journal of Alternative and Complementary Medicine* (2000 Dec) 6 (6) 557-9 (see Attachment A), the effectiveness of Ninjin Yoei To, an herbal medicine comprising glycyrrhize, was studied for treating patients suffering from lung cancer. The results of the study were that the tumors in the lungs were reduced and certain side effects, such as coughing, disappeared.

Perilla frutescens has been studied for decreasing the amount of nicotine and carbon monoxide contained in blood due to smoking and for reducing the effects of asthma. In JP 62-135428 a method of decreasing the amount of nicotine and carbon monoxide in the body of a smoker was described using an effective amount of a composition comprising the active ingredients of ascorbic acid or its salts, powdered leaves of Comfrey, vegetable albumin and *Perilla* (see Attachment B). It was discovered that this composition expedites or accelerates the natural body's process of detoxification.

In the *International Archives of Allergy and Immunology* Journal (See Attachment C), dietary *Perilla* seed oil was studied and it was determined that dietary supplementation of *Perilla* seed oil administered to selected patients with asthma suppresses the generation of leukotriene LTC4. It was also determined that clinical features such as an increase in respiratory function and a decrease in serum levels of total cholesterol, triglyceride, high-density lipoprotein cholesterol were also associated with *Perilla* seed oil. In *Internal Medicine*, (See Attachment D) the effects of *Perilla* seed oil on bronchial asthma were compared with the effects of corn oil. The results showed that *Perilla* seed oil supplementation is useful for the treatment of asthma in terms of suppression of LTB4 and LTC4 generation by leucocytes, and improves respiratory function.

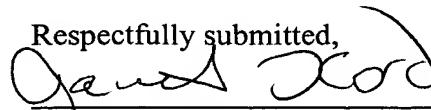
In *Chem. Pharm. Bull.* 43(5) 887-889 (1995), two novel antioxidants were produced from roasted *Perilla* seed, (see Attachment E). Antioxidants have been proven to prevent certain cancers, such as lung cancer, which is a side effect of smoking cigarettes.

The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination, *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed.Cir. 1990).

None of the prior art references cited by the Examiner suggest combining *Glycyrrhiza glabra* and *Perilla frutescens* with *Eucommia ulmoides* to reduce the side effects associated with the cessation of smoking. As noted above, it has been proven that *Glycyrrhiza glabra* reduces the side effect of coughing in patients suffering from lung cancer and *Perilla frutescens* improves respiratory functions in patients suffering from asthma.

Flavorants that may be used in the present invention include sodium chloride, glycerol, sweetener, spices, sugar, honey, and artificial sweetener, see page 3, lines 7-10. From the description in the specification along with the journal articles cited by the Applicants, it is clear that *Glycyrrhiza glabra* and *Perilla frutescens* are used for other purposes besides flavoring. Therefore, without the prior art suggesting using *Eucommia ulmoides*, *Glycyrrhiza glabra* and *Perilla frutescens* to overcome or moderate the physical effects associated with cessation of smoking, there is no suggestion or motivation to modify the reference or to combine the reference teachings.

Applicants respectfully submit that the present invention is nonobvious over the cited prior art because the references do not suggest the use of *Eucommia ulmoides*, *Glycyrrhiza glabra* and *Perilla frutescens* in an amount sufficient to overcome the coughing and respiratory effects associated with cessation of smoking.

Respectfully submitted,


JANET I. CORD
C/O LADAS & PARRY
26 WEST 61st STREET
NEW YORK, NEW YORK 10023
REG.NO. 33,778 (212)708-1935